

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

IN RE ANDROGEL ANTITRUST LITIGATION (NO. II)	Case No. 1:09-MD-2084-TWT END-PAYOR CLASS ACTIONS
FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, on behalf of itself and all others similarly situated,  Plaintiffs,  v. UNIMED PHARMACEUTICALS, INC., ET AL.,  Defendants.	Case No. 1:09-CV-2914-TWT
GEORGE STEVEN LEGRAND, on behalf of himself and all others similarly situated,  Plaintiffs,  v. UNIMED PHARMACEUTICALS, INC., ET AL.,  Defendants.	Case No. 1:10-CV-2883-TWT
HEALTH NET, INC., on behalf of itself and all others similarly situated, Plaintiffs,  v. UNIMED PHARMACEUTICALS, INC., ET AL.,  Defendants.	Case No. 1:11-CV-0334-TWT

**DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC.'S  
AND PADDOCK HOLDINGS, LLC'S ANSWER TO END-PAYOR  
PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT**

Defendants Par Pharmaceutical Companies, Inc. (“Par”) and Paddock Holdings, LLC (“Paddock”), by and through their attorneys, hereby respond to End-Payor Plaintiffs’ Consolidated Amended Complaint (“Amended Complaint”) in the above-referenced actions, filed August 5, 2014. Par/Paddock aver generally that the responses contained herein are with respect to the allegations directed to Par/Paddock only, as Par/Paddock are not required to respond to allegations set forth against any other Defendant. Par/Paddock generally deny each and every allegation that Par/Paddock do not expressly admit. Par/Paddock also specifically deny some allegations without affecting their general denial of other allegations.

Although not stated as an allegation, the first page of the Amended Complaint asserts that Paddock’s corporate predecessor, Paddock Laboratories, Inc., is now known as Perrigo Company. Paddock denies this assertion and answers on behalf of itself alone.

In addition to the above general answers, Par/Paddock provide the following answers to the specific allegations set forth in each numbered paragraph of the Amended Complaint:

1. Par/Paddock admit that this litigation alleges “unlawful exclusion from the market of low-cost AB-rated generic substitutes for the brand name

prescription drug AndroGel.” Par/Paddock deny the remaining allegations in Paragraph 1.

2. Par/Paddock admit that AndroGel is a brand name hormone replacement drug marketed by Solvay as a testosterone replacement therapy for males with a deficiency or absence of endogenous testosterone. Par/Paddock also admit that the active ingredient in AndroGel is synthetic testosterone. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 2, and therefore, deny the same.

3. To the extent that the allegations in Paragraph 3 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 3. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 3, and therefore, deny the same.

4. To the extent that the allegations in Paragraph 4 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 4. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 4, and therefore, deny the same.

5. Par/Paddock deny the allegations in Paragraph 5.

6. Par/Paddock deny the allegations in Paragraph 6.

7. Par/Paddock deny the allegations in Paragraph 7.

8. Paragraph 8 states legal conclusions to which no answer is required.

9. Paragraph 9 states legal conclusions to which no answer is required.

10. To the extent that the allegations in Paragraph 10 allege that Par/Paddock engaged in illegal conduct or caused Plaintiff Health Net, Inc. injury, Par/Paddock deny those allegations. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 10, and therefore, deny the same.

11. To the extent that the allegations in Paragraph 11 allege that Par/Paddock engaged in illegal conduct or caused Plaintiff Fraternal Order of Police injury, Par/Paddock deny those allegations. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 11, and therefore, deny the same.

12. To the extent that the allegations in Paragraph 12 allege that Par/Paddock engaged in illegal conduct or caused Plaintiff George S. LeGrand injury, Par/Paddock deny those allegations. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 12, and therefore, deny the same.

13. The allegations in Paragraph 13 do not apply to Par/Paddock.

14. To the extent that the allegations in Paragraph 14 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 14.

15. The allegations in Paragraph 15 do not apply to Par/Paddock.

16. Par admits that Par is a corporation organized under the laws of Delaware, that it maintains its principal place of business in Woodcliff Lake, New Jersey, and that it develops, manufactures, markets, and distributes pharmaceutical drug products.

17. Paddock denies that it is now known as Perrigo Company. Paddock Laboratories, Inc. is now known as Paddock Holdings, LLC, a limited-liability company registered in Minnesota. Paddock Holdings, LLC is not engaged in the business of developing, manufacturing, marketing, or distributing drug products, or any other business activity concerning drug products. Perrigo acquired assets of Paddock Laboratories, Inc. in 2011.

18. Paragraph 18 states legal conclusions to which no answer is required.

19. Paragraph 19 states legal conclusions to which no answer is required.

20. Paragraph 20 states legal conclusions to which no answer is required.

21. Paragraph 21 states legal conclusions to which no answer is required.

22. Paragraph 22 states legal conclusions to which no answer is required.

23. Paragraph 23 states legal conclusions to which no answer is required.

24. Paragraph 24 states legal conclusions to which no answer is required.
25. Paragraph 25 states legal conclusions to which no answer is required.
26. Paragraph 26 states legal conclusions to which no answer is required.
27. Paragraph 27 states legal conclusions to which no answer is required.
28. Paragraph 28 states legal conclusions to which no answer is required.
29. Paragraph 29 states legal conclusions to which no answer is required.
30. Paragraph 30 states legal conclusions to which no answer is required.
31. Paragraph 31 states legal conclusions to which no answer is required.
32. Paragraph 32 states legal conclusions to which no answer is required.
33. Paragraph 33 states legal conclusions to which no answer is required.
34. Paragraph 34 states legal conclusions to which no answer is required.
35. Paragraph 35 states legal conclusions to which no answer is required.
36. To the extent that the allegations in Paragraph 36 rely on publicly available documents, those documents speak for themselves.
37. Paragraph 37 states legal conclusions to which no answer is required.
38. Paragraph 38 states legal conclusions to which no answer is required.
39. To the extent that the allegations in Paragraph 39 rely on publicly available documents, those documents speak for themselves.

40. To the extent the allegations in Paragraph 40 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 40.

41. To the extent the allegations in Paragraph 41 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 41.

42. To the extent that the allegations in Paragraph 42 rely on publicly available documents, those documents speak for themselves.

43. To the extent that the allegations in Paragraph 43 rely on publicly available documents, those documents speak for themselves.

44. Paragraph 44 states legal conclusions to which no answer is required.

45. Paragraph 45 states legal conclusions to which no answer is required.

46. Paragraph 46 states legal conclusions to which no answer is required.

47. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 47, and therefore, deny the same.

48. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 48, and therefore, deny the same.

49. Par/Paddock admit that Solvay markets a branded prescription drug called AndroGel, which is a pharmaceutical gel containing synthetic testosterone. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 49, and therefore, deny the same.

50. Par/Paddock admit that Unimed Pharmaceuticals, L.L.C. (“Unimed”) and Laboratoires Besins Iscovesco (“Besins”) entered into agreements involving AndroGel, the terms of which speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 50, and therefore, deny the same.

51. Par/Paddock admit the allegations in Paragraph 51.

52. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 52, and therefore, deny the same.

53. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 53, and therefore, deny the same.

54. To the extent that the allegations in Paragraph 54 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 54, and therefore, deny the same.

55. To the extent that the allegations in Paragraph 55 rely on publicly available documents, those documents speak for themselves. The third sentence of Paragraph 55 states legal conclusions to which no answer is required. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 55, and therefore, deny the same.



56. To the extent that the allegations in Paragraph 56 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 56, and therefore, deny the same.

57. Par/Paddock admit that the U.S. Patent Office issued U.S. Patent No. 6,503,894 (the “894 Patent”) on or about January 7, 2003. To the extent that the allegations in Paragraph 57 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 57, and therefore, deny the same.

58. To the extent that the allegations in Paragraph 58 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 58, and therefore, deny the same.

59. To the extent that the allegations in Paragraph 59 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 59, and therefore, deny the same.

60. To the extent that the allegations in Paragraph 60 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 60, and therefore, deny the same.

61. To the extent that the allegations in Paragraph 61 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 61, and therefore, deny the same.

62. To the extent that the allegations in Paragraph 62 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 62, and therefore, deny the same.

63. To the extent that the allegations in Paragraph 63 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 63, and therefore, deny the same.

64. To the extent that the allegations in Paragraph 64 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack

knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 64, and therefore, deny the same.

65. To the extent that the allegations in Paragraph 65 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 65, and therefore, deny the same.

66. To the extent that the allegations in Paragraph 66 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 66, and therefore, deny the same.

67. To the extent that the allegations in Paragraph 67 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 67, and therefore, deny the same.

68. Par/Paddock admit that the '894 Patent issued on or about January 7, 2003. To the extent that the allegations in Paragraph 68 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 68, and therefore, deny the same.

69. Paragraph 69 states legal conclusions to which no answer is required. To the extent that the allegations in Paragraph 69 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 69, and therefore, deny the same.

70. Par/Paddock admit that the '894 Patent expires in August 2020 and that based on pediatric studies Solvay received regulatory exclusivity from the FDA that provides Solvay with an additional six months of exclusivity beyond the expiration of the '894 Patent. To the extent that the allegations in Paragraph 70 rely on publicly available documents, those documents speak for themselves.

71. To the extent that the allegations in Paragraph 71 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 71, and therefore, deny the same.

72. To the extent that the allegations in Paragraph 72 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 72, and therefore, deny the same.

73. To the extent that the allegations in Paragraph 73 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 73, and therefore, deny the same.

74. Paragraph 74 states legal conclusions to which no answer is required.

75. Paragraph 75 states legal conclusions to which no answer is required.

76. Paragraph 76 states legal conclusions to which no answer is required.

77. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first and second sentences of Paragraph 77, and therefore, deny the same. Par/Paddock deny the remaining allegations in Paragraph 77.

78. Par/Paddock deny participation in any “scheme.” The remaining allegations in Paragraph 78 state legal conclusions to which no answer is required.

79. Par/Paddock admit that the '894 Patent issued on or about January 7, 2003 and that Solvay listed the '894 Patent in the Orange Book as covering AndroGel or an approved method of using AndroGel. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 79, and therefore, deny the same.

80. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 80, and therefore, deny the same.

81. Paragraph 81 states legal conclusions to which no answer is required. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 81, and therefore, deny the same.

82. Paragraph 82 states legal conclusions to which no answer is required.

83. To the extent that the allegations in Paragraph 83 rely on publicly available documents, those documents speak for themselves. Paragraph 83 states legal conclusions to which no answer is required.

84. Paragraph 84 states legal conclusions to which no answer is required. To the extent that the allegations in Paragraph 84 rely on publicly available documents, those documents speak for themselves. Par/Paddock deny the remaining allegations in Paragraph 84.

85. Paragraph 85 states legal conclusions to which no answer is required.

86. To the extent that the allegations in Paragraph 86 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 86, and therefore, deny the same.

87. Paragraph 87 states legal conclusions to which no answer is required.

88. Paragraph 88 states legal conclusions to which no answer is required.

89. Paragraph 89 states legal conclusions to which no answer is required.

To the extent that the allegations in Paragraph 89 rely on publicly available documents, those documents speak for themselves.

90. Paragraph 90 states legal conclusions to which no answer is required.

91. Paragraph 91 states legal conclusions to which no answer is required.

92. Par/Paddock admit that in May 2003, Watson and Paddock each filed applications with the FDA to market a generic version of AndroGel, and as part of those applications, Paddock certified that, in the opinion of the applicant and to the best of its knowledge at that time, those generic products did not infringe the '894 Patent and that the '894 Patent was invalid. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 92, and therefore, deny the same.

93. Par/Paddock admit the allegations in Paragraph 93.

94. Par/Paddock admit that Par and Paddock partnered for the sharing of costs and risks associated with litigation, together with potential profits if there were a successful outcome, and for Par to market Paddock's generic product. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 94, and therefore, deny the same.

95. Par/Paddock admit that Paddock filed an ANDA containing a Paragraph IV certification for the '894 Patent, the terms of which speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 95, and therefore, deny the same.

96. Par/Paddock admit that in August 2003, Unimed and Besins filed patent-infringement lawsuits against Watson and Paddock, alleging that each infringed the '894 Patent. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 96, and therefore, deny the same.

97. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 97, and therefore, deny the same.

98. Paragraph 98 states legal conclusions to which no answer is required.

99. Paragraph 99 states legal conclusions to which no answer is required.

100. To the extent that the allegations in Paragraph 100 rely on publicly available documents, those documents speak for themselves.

101. Par/Paddock admit that Watson and Paddock filed counterclaims in the '894 Patent litigation, the terms of which speak for themselves.



102. Par/Paddock admit that Watson and Paddock filed motions for summary judgment in the '894 Patent litigation, the terms of which speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 102, and therefore, deny the same.

103. Par/Paddock admit that fact and expert discovery in the '894 Patent litigation concluded by July 2005, or thereabouts, and that the patent litigation settled in September 2006, or thereabouts.

104. To the extent that the allegations in Paragraph 104 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 104, and therefore, deny the same.

105. To the extent the allegations in Paragraph 105 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 105.

106. Par/Paddock admit that Paddock's ANDA received tentative approval from the FDA on or about October 27, 2004 and that Paddock's ANDA received final approval on or about May 27, 2007.

107. Par/Paddock admit that Watson's ANDA received final approval from the FDA on or about January 27, 2006. Par/Paddock also admit that according to

the FDA, Watson was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for the '894 Patent and was eligible for 180 days of generic drug exclusivity.

108. Paragraph 108 states legal conclusions to which no answer is required. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 108, and therefore, deny the same.

109. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 109, and therefore, deny the same. To the extent that the remaining allegations in Paragraph 109 rely on publicly available documents, those documents speak for themselves.

110. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 110, and therefore, deny the same. Par/Paddock admit that Solvay settled its patent litigations involving the '894 patent, the terms of which speak for themselves. Par/Paddock deny the remaining allegations in Paragraph 110.

111. To the extent that the allegations in Paragraph 111 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 111. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 111, and therefore, deny the same.

112. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 112, and therefore, deny the same.

113. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 113, and therefore, deny the same.

114. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 114, and therefore, deny the same.

115. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 115, and therefore, deny the same.

116. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 116, and therefore, deny the same.

117. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 117, and therefore, deny the same.

118. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 118, and therefore, deny the same.

119. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 119, and therefore, deny the same.

120. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 120, and therefore, deny the same.

121. Par/Paddock admit that Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court, the terms of which speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 121, and therefore, deny the same.

122. Par/Paddock admit the allegations in Paragraph 122.

123. Par/Paddock deny the allegations in Paragraph 123.

124. To the extent that the allegations in Paragraph 124 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 124. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 124, and therefore, deny the same.

125. Par/Paddock admit that Par entered into an agreement to co-promote AndroGel and Paddock entered into an agreement to serve as a back-up manufacturer for AndroGel, the terms of which speak for themselves. Par/Paddock deny the remaining allegations in Paragraph 125.

126. Par/Paddock admit that Par entered into an agreement to co-promote AndroGel and Paddock entered into an agreement to serve as a back-up manufacturer for AndroGel, the terms of which speak for themselves.

Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 126, and therefore, deny the same.

127. Par/Paddock admit that they entered into a written agreement to settle the '894 Patent litigation in September 2006, the terms of which speak for themselves.

128. Par/Paddock admit that Par and Paddock entered into a written agreement to transfer title of Paddock's ANDA to Par, the terms of which speak for themselves. Par/Paddock deny all remaining allegations in Paragraph 128.

129. Par/Paddock deny the allegations in Paragraph 129.

130. Par/Paddock admit that the district court hearing the '894 Patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment proposed by the parties, the terms of which speak for themselves.

131. To the extent that the allegations in Paragraph 131 rely on publicly available documents, those documents speak for themselves. Par/Paddock deny the remaining allegations in Paragraph 131.

132. To the extent that the allegations in Paragraph 132 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 132.

133. To the extent that the allegations in Paragraph 133 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 133.

134. To the extent that the allegations in Paragraph 134 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 134.

135. To the extent that the allegations in Paragraph 135 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 135.

136. To the extent that the allegations in Paragraph 136 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 136.

137. Par/Paddock admit that Perrigo Company acquired assets of Paddock Laboratories, Inc. in 2011. Par/Paddock deny the remaining allegations in Paragraph 137.

138. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 138, and therefore, deny the same.

139. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 139, and therefore, deny the same. Par/Paddock deny the remaining allegations in Paragraph 139.

140. To the extent that the allegations in Paragraph 140 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 140.

141. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 141, and therefore, deny the same. Par/Paddock deny the remaining allegations in Paragraph 141.

142. Par/Paddock deny the allegations in Paragraph 142.

143. To the extent that the allegations in Paragraph 143 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 143.

144. To the extent that the allegations in Paragraph 144 rely on publicly available documents, those documents speak for themselves. Par/Paddock deny the remaining allegations in Paragraph 144.

145. To the extent that the allegations in Paragraph 145 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 145, and therefore, deny the same.

146. To the extent that the allegations in Paragraph 146 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 146, and therefore, deny the same.

147. To the extent that the allegations in Paragraph 147 rely on publicly available documents, those documents speak for themselves. Par/Paddock lack knowledge or information sufficient to form a belief concerning the remaining allegations in Paragraph 147, and therefore, deny the same.

148. Paragraph 148 states legal conclusions to which no answer is required.

149. Paragraph 149 states legal conclusions to which no answer is required. Par/Paddock deny the remaining allegations in Paragraph 149.

150. To the extent that the allegations in Paragraph 150 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 150.

151. To the extent that the allegations in Paragraph 151 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 151.

152. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 152, and therefore, deny the same.

153. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 153, and therefore, deny the same.

154. To the extent that the allegations in Paragraph 154 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 154.

155. To the extent that the allegations in Paragraph 155 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 155.

156. Par/Paddock deny the allegations in Paragraph 156.

157. Par/Paddock deny the allegations in Paragraph 157.

158. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 158, and therefore, deny the same. Par/Paddock deny the remaining allegations in Paragraph 158.



159. Par/Paddock admit that Watson and Paddock filed ANDAs for FDA approval to market AB-rated generic equivalents to AndroGel. To the extent that the remaining allegations in Paragraph 159 apply to Par/Paddock, Par/Paddock deny the remaining allegations in Paragraph 159.

160. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 160, and therefore, deny the same.

161. Par/Paddock deny the allegations in Paragraph 161.

162. To the extent that the allegations in Paragraph 162 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 162.

163. To the extent that the allegations in Paragraph 163 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 163.

164. To the extent that the allegations in Paragraph 164 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 164.

165. To the extent that the allegations in Paragraph 165 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 165.

166. To the extent that the allegations in Paragraph 166 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 166.

167. To the extent that the allegations in Paragraph 167 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 167.

168. To the extent that the allegations in Paragraph 168 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 168.

169. To the extent that the allegations in Paragraph 169 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 169.

170. Paragraph 170 states legal conclusions to which no answer is required. To the extent that the remaining allegations in Paragraph 170 apply to Par/Paddock, Par/Paddock deny the remaining allegations in Paragraph 170.

171. Paragraph 171 states legal conclusions to which no answer is required.

172. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 172, and therefore, deny the same.

173. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in the first sentence of Paragraph 173, and therefore, deny the same. To the extent that the remaining allegations in Paragraph 173 apply to Par/Paddock, Par/Paddock deny the remaining allegations in Paragraph 173.

174. Paragraph 174 states legal conclusions to which no answer is required.

175. Paragraph 175 states legal conclusions to which no answer is required.

176. Paragraph 176 states legal conclusions to which no answer is required.

177. Paragraph 177 states legal conclusions to which no answer is required.

178. Paragraph 178 states legal conclusions to which no answer is required.

179. Paragraph 179 states legal conclusions to which no answer is required.

180. Paragraph 180 states legal conclusions to which no answer is required.

181. Paragraph 181 states legal conclusions to which no answer is required.

182. Par/Paddock lack knowledge or information sufficient to form a belief concerning the allegations in Paragraph 182, and therefore, deny the same.

183. Paragraph 183 states legal conclusions to which no answer is required.

184. Paragraph 184 states legal conclusions to which no answer is required.

185. Paragraph 185 states legal conclusions to which no answer is required.

186. Paragraph 186 states legal conclusions to which no answer is required.

187. Paragraph 187 states legal conclusions to which no answer is required.

188. Paragraph 188 states legal conclusions to which no answer is required.

189. Paragraph 189 states legal conclusions to which no answer is required.

190. Paragraph 190 states legal conclusions to which no answer is required.

191. Paragraph 191 states legal conclusions to which no answer is required.

**CLAIM I: MONOPOLIZATION UNDER STATE LAW**  
**(Asserted against Solvay)**

192. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

193. Paragraph 193 does not make any allegations, and therefore, requires no response.

194. Paragraph 194 makes no allegations against Par/Paddock, and therefore, requires no response.

195. Paragraph 195 makes no allegations against Par/Paddock, and therefore, requires no response.

196. Paragraph 196 makes no allegations against Par/Paddock, and therefore, requires no response.

197. Paragraph 197 makes no allegations against Par/Paddock, and therefore, requires no response.

198. Paragraph 198 makes no allegations against Par/Paddock, and therefore, requires no response.

199. Paragraph 199 makes no allegations against Par/Paddock, and therefore, requires no response.

**CLAIM II: CONSPIRACY TO MONOPOLIZE UNDER STATE LAW  
(Asserted against all Defendants)**

200. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

201. Paragraph 201 does not make any allegations, and therefore, requires no response.

202. To the extent that the allegations in Paragraph 202 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 202.

203. To the extent that the allegations in Paragraph 203 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 203.

204. To the extent that the allegations in Paragraph 204 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 204.

205. To the extent that the allegations in Paragraph 205 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 205.

206. To the extent that the allegations in Paragraph 206 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 206.

207. To the extent that the allegations in Paragraph 207 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 207.

208. To the extent that the allegations in Paragraph 208 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 208.

209. To the extent that the allegations in Paragraph 209 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 209.

210. To the extent that the allegations in Paragraph 210 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 210.

211. To the extent that the allegations in Paragraph 211 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 211.

**CLAIM III: CONSPIRACY AND COMBINATION IN RESTRAINT OF  
TRADE UNDER STATE LAW  
(Asserted against all Defendants)**

212. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

213. Paragraph 213 does not make any allegations, and therefore, requires no response.

214. To the extent that the allegations in Paragraph 214 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 214.

215. To the extent that the allegations in Paragraph 215 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 215.

216. To the extent that the allegations in Paragraph 216 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 216.

217. To the extent that the allegations in Paragraph 217 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 217.

218. To the extent that the allegations in Paragraph 218 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 218.

219. To the extent that the allegations in Paragraph 219 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 219.

**CLAIM IV: ATTEMPTED MONOPOLIZATION UNDER STATE LAW  
(Asserted against Solvay)**

220. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

221. Paragraph 221 does not make any allegations, and therefore, requires no response.

222. Paragraph 222 makes no allegations against Par/Paddock, and therefore, requires no response.

223. Paragraph 223 makes no allegations against Par/Paddock, and therefore, requires no response.

224. Paragraph 224 makes no allegations against Par/Paddock, and therefore, requires no response.

225. Paragraph 225 makes no allegations against Par/Paddock, and therefore, requires no response.

226. Paragraph 226 makes no allegations against Par/Paddock, and therefore, requires no response.

**CLAIM V: UNJUST ENRICHMENT  
(Asserted against all Defendants)**

227. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

228. To the extent that the allegations in Paragraph 228 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 228.

229. To the extent that the allegations in Paragraph 229 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 229.

230. To the extent that the allegations in Paragraph 230 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 230.

231. Paragraph 231 states legal conclusions to which no response is required. To the extent that the allegations in Paragraph 231 apply to Par/Paddock, Par/Paddock deny the remaining allegations in Paragraph 231.

232. Paragraph 232 states legal conclusions to which no response is required. To the extent that the allegations in Paragraph 232 apply to Par/Paddock, Par/Paddock deny the remaining allegations in Paragraph 232.

233. To the extent that the allegations in Paragraph 233 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 233.

234. To the extent that the allegations in Paragraph 234 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 234.

235. To the extent that the allegations in Paragraph 235 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 235.



236. To the extent that the allegations in Paragraph 236 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 236.

237. To the extent that the allegations in Paragraph 237 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 237 and any relief sought.

238. To the extent that the allegations in Paragraph 238 apply to Par/Paddock, Par/Paddock deny the allegations in Paragraph 238 and any relief sought.

239. Paragraph 239 states legal conclusions to which no response is required.

**CLAIM VI: DECLARATORY AND INJUNCTIVE RELIEF UNDER  
SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS'  
VIOLATIONS OF SECTION 1 AND SECTION 2 OF THE SHERMAN ACT  
(Asserted against all Defendants)**

240. Par/Paddock repeat and reassert all of the preceding and succeeding responses as if fully set forth herein.

241. Paragraph 241 states legal conclusions to which no response is required.

242. Paragraph 242 makes no allegations against Par/Paddock, and therefore, requires no response.

243. Paragraph 243 makes no allegations against Par/Paddock, and therefore, requires no response.

### **PLAINTIFFS' DEMAND FOR JUDGMENT**

244. Par/Paddock dispute that Plaintiffs are entitled to any relief whatsoever. Par/Paddock deny each and every allegation of the Amended Complaint not specifically admitted. Without assuming any burden that they would not otherwise bear, Par/Paddock assert the following affirmative defenses:

#### **FIRST AFFIRMATIVE DEFENSE**

245. The Amended Complaint fails to state a claim against Par/Paddock upon which relief may be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

246. Plaintiffs' claims are barred, in whole or in part, by the doctrine of *res judicata*.

#### **THIRD AFFIRMATIVE DEFENSE**

247. Plaintiffs' claims are barred, in whole or in part, by the doctrine of collateral estoppel.

#### **FOURTH AFFIRMATIVE DEFENSE**

248. Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations.

### **FIFTH AFFIRMATIVE DEFENSE**

249. Plaintiffs' claims are barred, in whole or in part, because Par/Paddock's actions were legal under the law of the Eleventh Circuit at the time they were taken. *See, e.g., Glazner v. Glazner*, 347 F.3d 1212, 1220 (11th Cir. 2003) (en banc) ("If this were truly a situation where the class of persons affected by the new rule would suddenly face a strong likelihood of liability when they faced no possibility of liability before, we would be inclined to view the equities as weighing heavily in favor of pure prospective application."); *Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 545 (11th Cir. 2002) (en banc) (applying new rule prospectively only: "It would be inequitable to punish those parties for following the clearly established precedent of this Circuit.").

### **SIXTH AFFIRMATIVE DEFENSE**

250. Plaintiffs' claims are barred, in whole or in part, because Par/Paddock's conduct was lawful under all applicable laws, statutes, ordinances, and decrees, including the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984, and related legislation.

### **SEVENTH AFFIRMATIVE DEFENSE**

251. Plaintiffs' claims are barred, in whole or in part, because the *Noerr-Pennington* doctrine immunizes Par/Paddock for the results achieved by and the

competitive impact of this Court's 2006 Consent Judgment and Order of Permanent Injunction.

#### **EIGHTH AFFIRMATIVE DEFENSE**

252. Plaintiffs' claims are barred, in whole or in part, because U.S. Patent No. 6,503,894 is valid, enforceable, and infringed by Par/Paddock's generic testosterone gel.

#### **NINTH AFFIRMATIVE DEFENSE**

253. Plaintiffs' claims are barred, in whole or in part, because there are no plausible allegations of harm to competition resulting from Par/Paddock, as the second ANDA filer, entering at the same date as Watson, the first ANDA filer—a more competitive outcome than Congress intended under the Hatch-Waxman regulatory scheme.

#### **TENTH AFFIRMATIVE DEFENSE**

254. Plaintiffs' claims are barred, in whole or in part, because the Amended Complaint fails to provide any economically plausible allegation for Par/Paddock as the second ANDA filer to have continued to litigate its separate patent-infringement suit, *Unimed Pharms., Inc. et al. v. Paddock Labs., Inc.*, Civil Action No. 1:03-cv-02503-TWT (N.D. Ga.), in lieu of settling in 2006, particularly after Watson, the first ANDA filer, settled—especially under the Hatch-Waxman

regime as it existed prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003), which governed the ANDAs at issue in this matter.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

255. Plaintiffs' claims are barred, in whole or in part, because even assuming *arguendo* that the antitrust laws applied and assuming further *arguendo* that the alleged conduct had any potential anticompetitive effect, Par/Paddock's settlement agreement with Unimed and Besins is governed by the rule of reason and is lawful, as its procompetitive benefits outweigh any alleged anticompetitive effect.

#### **TWELFTH AFFIRMATIVE DEFENSE**

256. Plaintiffs' claims are barred, in whole or in part, because Par/Paddock's alleged conduct was reasonable and based on independent, legitimate business and economic justifications.

#### **THIRTEENTH AFFIRMATIVE DEFENSE**

257. Plaintiffs' claims are barred, in whole or in part, because the co-promotion and back-up manufacturing deals Solvay and Unimed entered into with Par/Paddock did not involve any large and unjustified payment, but rather value for services that were fair and/or justified under the circumstances.

#### **FOURTEENTH AFFIRMATIVE DEFENSE**

258. Any and all of Par/Paddock's actions alleged by Plaintiffs were lawful, justified, procompetitive, carried out in furtherance of Par/Paddock's legitimate business interests, and constitute *bona fide* competition.

#### **FIFTEENTH AFFIRMATIVE DEFENSE**

259. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged injury and the alleged injury to competition, if any, is too speculative and uncertain.

#### **SIXTEENTH AFFIRMATIVE DEFENSE**

260. Plaintiffs' claims are barred, in whole or in part, because the acts or omissions of Par/Paddock did not substantially lessen competition in any properly defined market.

#### **SEVENTEENTH AFFIRMATIVE DEFENSE**

261. Plaintiffs' claims are barred, in whole or in part, because no consumer, entity, or individual has suffered injury proximately caused by any conduct of Par/Paddock and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

### **EIGHTEENTH AFFIRMATIVE DEFENSE**

262. Plaintiffs' claims are barred, in whole or in part, because the acts or omissions of Par/Paddock did not result in any significant anticompetitive effects in any properly defined market.

### **NINETEENTH AFFIRMATIVE DEFENSE**

263. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have failed to properly allege a relevant product market and a relevant geographic market.

### **TWENTIETH AFFIRMATIVE DEFENSE**

264. Plaintiffs' claims are barred, in whole or in part, because Solvay lacks market power in any properly defined relevant market.

### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

265. Plaintiffs' claims are barred, in whole or in part, under the *Trinko* doctrine and its progeny because any harm to competition complained of stems from the intricate, multi-tiered regulatory regime, which governs the production, sale, and manufacture of pharmaceutical products, including the Hatch-Waxman Act.

### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

266. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack standing to bring or maintain this action. Plaintiffs also lack standing to bring its claims because the putative class members that Plaintiffs purport to represent have not suffered antitrust injury or injury in fact.

### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

267. Plaintiffs' claims are barred, in whole or in part, because their alleged damages, if any, are speculative, and because of the impossibility of the ascertainment and allocation of those alleged damages.

### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

268. Plaintiffs' claims are barred, in whole or in part, because this action is not properly certifiable or maintainable as a class action.

### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

269. To the extent there is a finding of an illegal overcharge, Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs passed on the effect of such an overcharge to a third party.

### **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

270. To the extent there is a finding of an illegal overcharge, Plaintiffs' claims are barred, in whole or in part, to the extent that such overcharge was



absorbed, in whole or in part, by direct purchasers, and was not absorbed by the indirect purchasers.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

271. Plaintiffs would be unjustly enriched if allowed to recover any relief claimed to be due.

#### **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

272. Plaintiffs are barred from recovery of any damages because of and to the extent of their failure to mitigate any such damages.

#### **TWENTY-NINTH AFFIRMATIVE DEFENSE**

273. Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs seek damages that would constitute duplicative recovery for the same conduct.

#### **THIRTIETH AFFIRMATIVE DEFENSE**

274. Plaintiffs have an adequate remedy at law and no factual or legal basis for the grant of equitable relief.

#### **RESERVATION OF DEFENSES AND AFFIRMATIVE DEFENSES**

275. Par/Paddock reserve the right to assert and rely on any additional defenses and affirmative defenses that may come available or apparent, and to amend their answer and/or defenses.

### **PRAYER FOR RELIEF**

Wherefore, Par/Paddock demand judgment against the Plaintiffs as follows:

1. Deny any and all relief requested under Plaintiffs' Amended Complaint;
2. For costs of suit incurred and for reasonable attorneys' fees; and
3. Awarding Defendants such other and further relief as the Court deems just and proper.

Respectfully submitted, this 15th day of September 2014.

/s/ Eric Grannon

Eric Grannon\*

J. Mark Gidley\*

Adam M. Acosta\*

WHITE & CASE LLP

701 Thirteenth Street, N.W.

Washington, DC 20005

(202) 626-3600 (telephone)

(202) 639-9355 (facsimile)

egrannon@whitecase.com

mgidley@whitecase.com

adam.acosta@whitecase.com

\*Practicing pursuant to the Initial  
Case Management Order

*Counsel for Defendants Par*

*Pharmaceutical Companies, Inc.*

*& Paddock Holdings, LLC*

Mark G. Trigg

Georgia Bar No. 716295

GREENBERG TRAURIG, LLP

Terminus 200

3333 Piedmont Road, Suite 2500

Atlanta, GA 30305

(678) 553-2100 (telephone)

(678) 553-2212 (facsimile)

triggm@gtlaw.com

*Counsel for Defendants Par*

*Pharmaceutical Companies, Inc.*

*& Paddock Holdings, LLC*